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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------|------------------|
| 10/729,742 | 12/05/2003 | Stephen Griffin | 1001.1727101 | 1334 |
| 28075 | 7590 | 04/10/2006 | EXAMINER | |
| CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420 | | | DRYDEN, MATTHEW DUTTON | |
| | | ART UNIT | PAPER NUMBER | |
| | | 3736 | | |

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/729,742 | GRIFFIN ET AL. | |
| | Examiner | Art Unit | |
| | Matthew D. Dryden | 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 December 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 05 December 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/18/04, 5/13/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Rammler (5327891).

Regarding claim 1, Rammler discloses a catheter comprising:

an elongate shaft having a proximal region, a distal region and an exterior surface extending there between (see Figure 1, around elements 12 and 20, where in the distal end is seen in Figure 1, and the proximal end is at the other end of tube 10 in Figure 1),

removable support means capable of providing column support to the elongate shaft, disposed at least a portion of the exterior surface of the elongate shaft can be seen in Figure 1 as element 24, and element 60 in Figure 3.

Regarding claim 2, the anchoring means can be seen around element 22 in Figure 1, and around element 32 in Figure 2.

Regarding claim 3, the anchoring means has a cross-sectional profile configured to permit the movable support means to move axially with respect to the elongate shaft while limiting relative radial movement (see Figure 2, around element 32).

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Regarding claim 4, the anchoring means comprises one or more support tracks disposed on the exterior surface of the elongate shaft (see Figure 1 around elements 16.).

Regarding claim 5, the support means does comprise a support rib configured to be disposed over the one or more support track, see around element 24 in Figure 1, and around element 86 in Figure 4.

Regarding claim 6, the support ribs slide axially over each of the one or more support tracks (see Column 5, lines 36-41).

Regarding claim 7, see Columns 2-3, lines 66-11.

Regarding claim 8, the support means as discussed in the rejection of claim 2 can be viewed as a sheath.

Regarding claim 22, Rammler discloses a method comprising:
advancing the catheter through the vascular lumen until the distal end of the elongate shaft reaches a desired position (see Column 5, lines 36-41),
and deploying one or more support ribs over one or more support tracks and advancing the one or more support ribs over the tracks (see Column 4, lines 16-20).

Regarding claim 23, see Columns 5-6, lines 57-13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9, 10, 14, 15, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rammler in view of Stevens-Wright et al (5715817). Rammler discloses the claimed invention except for the device comprising a plurality of support ribs that are configured to be removably disposed over the tracks. Stevens-Wright et al teach it is known to provide a catheter with a plurality of reinforcement members (elements 62 in Figures 10 and 11) disposed on a plurality of tracks (elements 64 in Figure 10), to allow for greater control of the tip of the catheter while it is being maneuvered through the body (see Columns 4-5, lines 36-50) and to allow bidirectional steering of the catheter (see Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rammler with a plurality of support ribs, as taught by Stevens-Wright et al, to allow for greater control of the tip of the catheter while it is being maneuvered through the body and to allow bidirectional steering of the catheter.

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Regarding claim 10, the support tracks have a cross-sectional profile configured to permit the movable support means to move axially with respect to the elongate shaft while limiting relative radial movement (see Figure 2, around element 32).

Regarding claim 14, the support ribs do have a cross-section profile complementary to the cross-section profile of each of the plurality of support tracks (see Figure 4 around element 86).

Regarding claim 15, see Columns 2-3, lines 66-11.

Regarding claims 19 and 20, see Column 3, lines 21-23, and Column 4, lines 27-30.

Regarding claim 21, the distal region of the elongate shaft of Rammler includes a distal end, and the tracks extend from a proximate position to the distal end of the shaft (see Figure 1).

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rammler in view of Stevens-Wright et al as applied to claim 10 above, and further in view of Beckman et al (5957979). Rammler discloses the claimed invention except for the support tracks comprising an ovoid cross section, wherein the major dimension varies as a function of distance and is minimized at a proximate position of the exterior surface of the shaft. However Rammler does disclose the track having a variety of different shapes, which could include an ovoid shaped cross section. Beckman et al teach it is known to provide an anchoring means comprising an ovoid section (see around element 34 in Figure 1) the ovoid cross section provides a more stable locking arrangement between the ribs and the track. It would have been obvious to one having

ordinary skill in the art at the time the invention was made to modify the device of Rammler with an anchoring mechanism comprising an ovoid cross section, as taught by Beckman et al, to provide a more stable locking arrangement between the ribs and the track.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rammler in view of Stevens-Wright et al as applied to claim 9 above, and further in view of MacDonald et al (6210396). Rammler discloses that it is known to attach the tracks to the catheter but does not go into detail on how to attach the tracks. MacDonald et al teach it is known to attach a portion of the catheter by using either heat bonding or adhesives, to provide a stable attachment method for attaching a portion to the exterior of the catheter (see Column 9, lines 58-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to attach the tracks by either heat bonding or adhesives, as taught by MacDonald et al, to provide a stable attachment method for attaching a portion to the exterior of the catheter.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rammler in view of Stevens-Wright et al as applied to claim 9 above, and further in view of Jang (6730037). Rammler discloses that it is known to attach the tracks to the catheter but does not disclose to form them integrally with the elongate shaft. Jang teaches it is known to provide tracks (lumens) with a catheter and to form them by extrusion (see Column 6, lines 59-61), which in turn would decrease the cost of making the system. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rammler by providing the catheter with

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tracks formed integrally through extrusion, as taught by Jang, to decrease the cost of making the system.

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rammler. Rammler discloses the claimed method except for the method comprising a step of withdrawing the treatment device from the catheter while the one or more support ribs remained in place, and a step of withdrawing the one or more support ribs after withdrawing the treatment device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to remove the treatment device while the support ribs remained in position to prevent possible injury to the patient, because in one embodiment of Rammler a retractable knife is used for biopsy and if the support ribs were removed the knife could damage either the catheter or surrounding tissues, so this step would be obvious for safety measures. Also, it would have been obvious to one having ordinary skill in the art at the time the invention was made to remove the support ribs after withdrawing the treatment device for the reasons discussed above and so that the entire catheter system could be removed from the body.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 6,607,496 Poor et al disclose a steerable stylet with enhanced torsional transfer strength

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U.S. Pat. No. 6,873,868 Furnish discloses a multi-fiber catheter probe arrangement for tissue analysis or treatment

U.S. Pat. No. 3,674,014 Tillander discloses a magnetically guidable catheter-tip and method.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Dryden whose telephone number is (571) 272-6266. The examiner can normally be reached on Monday-Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MDD

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ART UNIT 3736
MAILING CENTER 3700